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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,905	10/07/2003	Stephen D. Pacetti	50623.243	6361
7590 01/18/2008				
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		EXAMINER		
		CAMERON, ERMA C		
		ART UNIT		PAPER NUMBER
		1792		
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		01/18/2008		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/680,905

Applicant(s)

PACETTI ET AL.

Examiner

/Erma Cameron/

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-9, 11-18 and 20-44 is/are pending in the application.
- 4a) Of the above claim(s) 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5-9, 11-18, 20-24, 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment*

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is new matter that was not in the specification as originally filed:

Claim 42	“or any combinations thereof”
Claim 43	“applied...in a continuous manner”
Claim 44	“applied...in a continuous manner”

The examiner cannot find where any of these concepts are supported in the specification.

The applicant is requested to remove all new matter.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of Claims 1, 4, 5, 7-11, 16-20, 23, 24 under 35 U.S.C. 102(b) as being anticipated by Schueller et al. (US 2002/0050220) is withdrawn because of the amendment filed 10/29/2007.

5. Claims 1, 5, 7-9, 16, 17, 41 and 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by RD 434009, June 2000.

RD article number 434009 teaches a method (see entire article) of coating a tubular stent by mounting the stent on a mandrel, and rolling the stent on a carrier such as a sponge soaked with the coating composition, i.e. applicator with a layer of coating composition, and transferring at least some of the coating composition onto the outer surface of the stent (see Figure 1). An alternative is to rotate the stent on the mandrel while supported in a cup E filled with therapeutic agent D. The cup is lined with a sponge C soaked with the therapeutic solution D. The coating composition comprises therapeutic agent, a solvent to create the solution or suspension, and a polymer. The coating is applied in a continuous manner.

***Response to Arguments***

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The applicant has argued that RD'009 teaches a stent precoated with polymer. This is correct. However, RD'009 also teaches that the coating composition contains therapeutic agent D, as well as a polymer that acts as a matrix, and a solvent to create the suspension or solution.

The applicant has also argued that, regarding claim 41, the cup is not actually filled with liquid. The examiner disagrees. RD'009 teaches "a cylindrical cup (E) filled with therapeutic agent solution". The meaning could not be more clear.

6. Claims 1, 5, 7-9, 13, 14, 18, 20, 22-24 and 43-44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Castro et al (6395326).

'326 teaches an applicator system for applying coatings (polymer/solvent/drug) to stents. Both the applicator system and the stent may revolve around each other (Figures 1-5), and the stent is mounted on a mandrel (7:32-9:67). Air pressure may be applied to the coating in the dispenser, thus serving to level it (9:25-38). It appears that the applicator follows the curvature of the struts, thus having the same radius of curvature. Application may be intermittent or continuous (9:25-37).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2, 3, 6, 11-13 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over RD 4343009.

Research Disclosure Database Number 434009 is applied here for the reasons given above.

RD'009 does not specifically teach the thickness of the coating layer on the applicator surface, the viscosity of the coating solution or the speed of rotation of either Figure 1 or Figure 2 embodiments. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the thickness, viscosity and speed of rotation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See M.P.E.P 2144. 05 IIB.

It appears that the inner surface of the stent would not be coated, at least in the embodiment of Figure 1 because the stent is mounted on a mandrel that rests against its inner surface.

RD'009 does not teach that the sponge or cloth soaked with the coating solution is grooved, but that would be an obvious variation.

9. The rejection of Claims 9, 12-15 and 22 under 35 U.S.C. 103(a) as being unpatentable over by Schueller et al. ('220) in view of Pacetti et al. (6,565,659) is withdrawn because of the amendment filed 10/29/2007.

10. The rejection of Claim 21 under 35 U.S.C. 103(a) as being anticipated by Schueller et al. (US 2002/0050220) is withdrawn because of the amendment filed 10/29/2007.

11. Claims 2, 3, 6, 11, 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (6395326).

‘326 is applied here for the reasons given above.

‘326 does not specifically teach the thickness of the coating layer on the applicator surface, the viscosity of the coating solution or the speed of rotation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the thickness, viscosity and speed of rotation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See M.P.E.P 2144. 05 IIB.

It appears that the inner surface of the stent would not be coated because the stent is mounted on a mandrel that rests against its inner surface.

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (6395326) taken in view of Zarbatany et al (6610087).

‘326 is applied here for the reasons given above.

‘326 fails to teach a barrier to coating application as in claim 15.

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'087 teaches that a barrier or mask may be used to alter the amount of coating applied to particular places on a stent (14:32-53).

It would have been obvious to one of ordinary skill in the art to have used the barrier or mask of '087 in the '326 application process as an easy way to modify where coating and how much coating is applied.

### ***Response to Amendment***

13. The Declaration filed on 10/29/2007 under 37 CFR 1.131 has been considered but is ineffective: the declaration lacks a statement that the application and reference were both subject to an obligation of assignment at the time the invention was made.

### ***Drawings***

14. The examiner apologizes for requesting a prior art designation for figure 1 that already existed.

### ***Conclusion***



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15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erma Cameron/  
Primary Examiner  
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January 17, 2008